K06 1421

JUL 25 2006

510(k) SUMMARY

In accordance with the provisions of the Safe Medical Device Act of 1990, eRAD Inc. (Image Medical Corp)., is providing a summary of safety and effectiveness information regarding the eRAD PACS , Picture Archiving and Communications System.

1.1 Company Identification

eRAD Inc. (Image Medical Corp.)
9 Pilgrim Road
Greenville SC 29607.
Establishment Registration: 2954766
Owner Operator Number: 9042966
Contact: Jim Connors, Vice President, Product Management
Tel: (864) 640-8664
Fax: (864) 234-7412

1.2 Official Correspondent

Gary J. Allsebrook, Consultant
Regulatory Management Services
16303 Panoramic Way
San Leandro CA USA 94578-1116
Tel/fax: (510) 276-2648
Cell: (510) 388-5001
Email: regman10@comcast.net

1.3 Date of Submission

May 16, 2006

1.4 Device Name

Classification Name:	PACS
Common/Usual Name:	Soft-copy reading and acquisition system
Proprietary Name:	eRAD PACS

1.5 Substantial Equivalence

eRAD PACS has indications for use and a target population similar to other medical image management devices, including Stentor's iSite (K013630) and Stentor's iVault (Class I Exempt), Agfa's IMPAX (K022292), Ultravisual's Vortex (K012097) and Dynamic Imaging's INTEGRADWeb MPR/MIP (K042313). All of the functions eRAD PACS performs are available in at least one of the listed substantially equivalent devices. In most cases, the function is available in all of

them. There are no significant differences between eRAD PACS and the collective functions of all the predicate devices.

1.6 Device Description and Intended Use

eRAD PACS is a PACS system, comprised of acquisition components (GatewayServer and SendServer), a central system manager component (SmartServer), a diagnostic workstation component (Workstation and Viewer), and an archiving component (ArchiveServer). The data flow is such that patient and procedure information is optionally delivered to the central system manager, followed by the acquisition of the image objects directly from the image sources or by one of the acquisition components. After receiving the procedure information or after receiving image objects, the central system manager searches for and retrieves relevant prior procedure data from the archive component. When the central system manager registers the acquired image objects and the retrieved prior procedure data, a user can access the information by selecting the item from the operator worklist. The image data is transmitted to and rendered on the user's workstation using the diagnostic workstation components. After using the workstation to view the images, the user optionally dictates a report into the system, after which, a user can play back the dictation and transcribe it to text. Once eRAD PACS's central system manager registers a report, the report is available for access by the referring physician, or it can be exported into an information system. At some configured point in time, the image data and the report information is delivered to the archiving component for backup and long-term storage.

eRAD PACS is a PACS and teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. eRAD PACS is for hospitals, imaging centers, radiologist reading practices and any user who requires and is granted access to patient image, demographic and report information.

1.7 Software Development

eRAD Inc., certifies that the eRAD PACS software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field

maintenance. The software developed for this product is used to provide diagnostic quality images and associated information for the intended users.

1.8 Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any warnings or cautions to provide for the safe and effective use of the device. It is the user's responsibility to insure that display quality, environmental lighting and other possible distractions are consistent with a clinical environment. .The hardware components specified are all "off the shelf" computer components.

It is our conclusion that there is no software or hardware component in the eRAD PACS device, which would be used in conjunction with the eRAD PACS device, that we know of, whose failure or latent design flaw would be expected to result in death or injury to a patient. Thus the "level of concern" on the eRAD PACS device is "minor".

Substantial Equivalence Summary:

eRAD PACS is substantially equivalent in design and intended use to diagnostic workstations, PACS and image management systems and substantiated in the feature comparison. Any differences between the eRAD PACS and the predicate devices have no significant influence on safety and effectiveness. eRAD PACS, therefore, raises no new issues of safety or effectiveness from the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 25 2006

eRad, Inc.
% Mr. Gary J. Allsebrook
Consultant
Regulatory Management Services
16303 Panoramic Way
SAN LEANDRO CA 94578

Re: K061421
Trade/Device Name: eRAD PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 19, 2006
Received: May 22, 2006

Dear Mr. Allsebrook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K061421

Device Name: eRAD, Inc (Image Medical Corp.) ***eRAD PACS***
Picture Archiving and Communications System

Indications For Use:

eRAD PACS is a PACS and teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. eRAD PACS is for hospitals, imaging centers, radiologist reading practices and any user who requires and is granted access to patient image, demographic and report information.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061421